

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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OTIS WATKINS and MCKINLEE PRUETT, \*  
Individually and as Representatives \*  
of a Proposed Class, \*  
Plaintiffs, \*

v. \*

C.A. No. 1:09-cv-10857-RGS

OMNI LIFE SCIENCE, INC., \*  
Successor to \*  
APEX SURGICAL, LLC, \*  
Defendant. \*

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**REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**

**I. INTRODUCTION**

Plaintiffs pursue a class action on behalf of individuals with functioning Apex hip implants that have not failed, alleging that “uniform representations and warranties” misled class members. Their Memorandum in Opposition to Motion to Dismiss (“Opposition”) requires several rejoinders;

1. Plaintiffs seek application of Massachusetts law but do not plead facts sufficient to perform the “flexible interest-based” choice of law calculus required in Massachusetts. This failure is significant as the law most likely to be applicable is that of the state where Plaintiffs’ surgery took place. That state is likely to be Oklahoma, where Plaintiffs reside. Oklahoma law would bar this claim.
2. Exhibit 1 to the Opposition establishes that the Apex hip is a medical device approved by the FDA and implanted by learned intermediary doctors. While Plaintiffs allege misrepresentations in general, as if

this were a consumer appliance, the only statements that matter are communications from the company to the doctors who selected and implanted this device. Plaintiffs make no allegation that the actual package insert to physicians was faulty in any way.

3. Plaintiffs also do not allege specifics as to the alleged “uniform representations and warranties” and identify no false representations by Apex to any consumer, making those allegations mere rote repetitions of the elements of a claim they wish to allege, but do not. The only instances of “representations” that Plaintiffs do cite are not directed to consumers and the statements actually made are not alleged to be false.
4. Plaintiffs do not allege facts sufficient to show defect or injury under any state’s laws. Exhibit 1 to the Opposition establishes that the Apex hip was approved by the FDA as substantially equivalent to other artificial hips based on tests the FDA reviewed. Plaintiffs do not allege that the Apex hip failed more often than competing products, only that the Apex hip was “substantially likely to fail.” E.g., Complaint at ¶¶ 34, 44. In their Opposition, they mischaracterize the findings of the one survey article on hip failures that they do cite. The Apex hip failure rate is in line with the failure rate of competing artificial hips. If Oklahoma law applies, they have not alleged any actual injury. If Massachusetts law were to apply, they have not alleged a cognizable injury.

5. Plaintiffs do not plead a plausible claim to be intended third party beneficiaries of some contract or for unjust enrichment. There is no basis to infer that anyone intended that Plaintiffs could enforce a contract to purchase a medical device. There is no basis to infer that Plaintiffs suffered any unjust detriment, not least because Plaintiffs acknowledge they did not purchase the hips.

## II. FAILURE TO ALLEGE FACTS SUFFICIENT TO SUPPORT A CHOICE OF MASSACHUSETTS LAW

Plaintiffs are Oklahoma residents. Complaint at ¶¶ 11, 12. They assert that Massachusetts law governs their claims because Apex is in Massachusetts and important decisions were made by that Massachusetts company. Complaint at ¶¶ 47-48. But Massachusetts choice of law rules require a weighing of facts that Plaintiffs pointedly ignore. In Massachusetts, tort claims involve a “flexible interest-based” choice of law calculus. Millipore Corp. v. Travelers Indem. Co., 115 F.3d 21, 30 (1<sup>st</sup> Cir. 1997); Value Partners S.A. v. Bain & Co., Inc., 245 F. Supp. 2d 269, 276 (D. Mass. 2003). Claims for breach of warranty under c. 93A are considered tort claims for choice of law purposes. Crellin Tech. Inc. v. Equipment Lease Corp., 18 F.3d 1, 11 (1<sup>st</sup> Cir. 1994). Specific factors to be weighed include, 1) place of injury, 2) place of conduct, 3) domicile of the parties, and 4) the place where the relationship between the parties is centered. Value Partners, 245 F. Supp. 2d at 276. General factors include the needs and policies of other interested jurisdictions, protection of justified expectations, certainty, predictability and uniformity of results. See Reichler v. Berkshire Life Ins. Co., 360 F.3d 1, 5 (1<sup>st</sup> Cir. 2004); Millipore, 115 F.3d at 30; see also Restatement (2d) of Conflicts of Laws § 6(2).

These factors suggest strongly that the law of the state where the patient dealt with her doctor and received the hip implant will supply the applicable law.

Choice of law is critical because the laws of states vary significantly. Taking Oklahoma as a potential source of law for the Oklahoma resident Plaintiffs, the differences as against Massachusetts law include the following:

a. Actual Injury. Oklahoma requires an actual injury as a predicate to a claim under the Oklahoma Consumer Protection Act (“OCPA”), Okla. Stat. tit. 15, § 761.1. The Supreme Court of Oklahoma held that “a person may not bring an action as an aggrieved consumer under [the OCPA] solely as a result of his or her payment of the purchase price for that product. An essential element of a claim under [the OCPA] is actual injury or damage caused by a violation of the OCPA.” Walls v. American Tobacco Co., 11 P.3d 626, 630 (Okla. 2000). “Courts do not allow consumers to bring claims against manufacturers for products that are perceived to be harmful, but that have not actually cause[d] an identifiable injury.” Harrison v. Leviton Manufacturing Co., Inc., No. 05-CV-0491-CVE-FHM, 2006 U.S. Dist. LEXIS 76334, at \*14 (N.D. Okla. Oct. 19, 2006) (plaintiff who wanted to replace allegedly defective electric wiring that had not caused damage to his home did not sustain an injury). The same requirement of actual injury is required for a claim of breach of implied warranty and unjust enrichment. Id. at \*17, \*20.

The nature of actual injury under Massachusetts c. 93A is less settled and considerably more convoluted. While Plaintiffs have not alleged injury under the Massachusetts statute, either, see Memorandum in Support of Motion to Dismiss (“Memorandum”) at 16-17, Massachusetts may not require the occurrence of an actual

injury other than loss of the benefit of the bargain to support a claim. See Iannacchino v. Ford Motor Co., 451 Mass. 623, 630 (2008). At the least, the currently fluid state of Massachusetts law is in marked contrast to the bright line test of actual injury in Oklahoma.

b. Statute of Limitations. Oklahoma and Massachusetts also have different statutes of limitations for consumer protection and warranty claims. Oklahoma has a three year statute of limitations for damages claims under the OCPA. See Brashears v. Sight N Sound Appliance Centers, Inc., 981 P.2d 1270, 1274 (Okla. Civ. App. 1999). Perhaps more significantly, Oklahoma has a five year limitation on claims for breach of implied warranty accruing when the breach occurs regardless of the aggrieved party's lack of knowledge of the breach. Okla. Stat. tit. 12A, § 2-725(1)-(2) .

In Massachusetts, the statute of limitations for c. 93A is four years, Mass. Gen. Laws c. 260, § 5A, and a breach of warranty for personal injury must be made within three years, Mass. Gen. Laws c. 260, § 2A. While this claim is for no injury, the tort statute for breach of warranty appears to be the best fit.

The likelihood is that the law of the state where the Plaintiffs dealt with their doctors and underwent surgery will supply the applicable law governing these claims. Plaintiffs have not alleged facts that give them a "plausible entitlement" to be governed by Massachusetts law. The Complaint based on Massachusetts law should be dismissed.

**III. PLAINTIFFS DO NOT ALLEGE ANY MISREPRESENTATIONS TO LEARNED INTERMEDIARY DOCTORS, AND DO NOT ALLEGE FACTS THAT SHOW ANY MISREPRESENTATIONS TO PLAINTIFFS**

The Opposition, at Exhibit 1, establishes that the Apex hip was an FDA approved medical device. Plaintiffs' Complaint and Opposition are couched as if the device were an off the shelf consumer gadget and the claims of "uniform representations and

warranties” to the class are stated as if they misled a consumer choice. See, e.g., Complaint at ¶¶ 42-45. To the contrary, the duty of Apex was to give adequate warnings and instructions to the learned intermediary physician who cared for Plaintiffs. See Memorandum at 15-16. As Plaintiffs themselves note, “[c]onsumers of medical implants rarely have the necessary experience to select the proper implant for their specific needs and instead rely on their surgeon’s advice”. Opposition at 3, n. 2. Focus on the role of the learned intermediary shows that the bulk of Plaintiffs’ allegations of misrepresentations are just beside the point.

Plaintiffs assert that the defense of “learned intermediary” is an affirmative defense with the burden on Defendant. Opposition at 12-15. That is not accurate. Plaintiffs have the burden to prove that a learned intermediary was inadequately warned or instructed and that the use of the Apex device was caused by that inadequacy; Defendant may have the burden to show that the doctor would have proceeded no matter what warning or instruction was given. See Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1<sup>st</sup> Cir. 1992) (“[P]laintiff carries the initial burden of producing sufficient evidence that the Defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known ...”). The point, however, is not what any learned intermediary actually did but that Plaintiffs have not alleged facts sufficient to raise a “plausible” claim that any physician was misinformed or under-informed by Apex. Medical device companies must inform physicians about these devices. There is no allegation whatever as to what Apex told the physicians to guide their decisions.

Further, Plaintiffs allege no facts about representations from Apex to the Plaintiffs or class, nor could they as Apex did not promote or sell its products to consumers, to

Plaintiffs or the alleged class. The allegations of “uniform representations and warranties” are empty of content and do not set out a “plausible entitlement to relief” as required by Ashcroft v. Iqbal, 129 S. Ct. 1937, 1950 (2009) or Gagliardi v. Sullivan, 513 F.3d 301, 305 (1<sup>st</sup> Cir. 2008). Plaintiffs attach three exhibits to their Complaint. Exhibits 2 and 3, from 2006, are conspicuously irrelevant as they post-date the changes Apex made in its device. Each of those exhibits details “Apex Improvements” as completed. See Ex. 2 and Ex. 3 to Complaint. Exhibit 1, an article in the Joint Implant Surgery and Research Foundation Update series, describes the then new device with cautionary “Early impressions as a group,” citing both encouragement and the need for long term outcome data. See Ex. 1 to Complaint at 5. Plaintiffs nowhere allege that they were aware of this Update, that it had wide circulation or that it had any influence on any implantation decision. An article in a journal, balanced at that, is no basis to infer “uniform representations and warranties” to the Plaintiffs. There is equally no reason to infer that this 2002 article was a misrepresentation as Plaintiffs allege that the first Apex hips to fail did so in 2004. See Complaint at ¶ 35. Just as significantly, Plaintiffs do not assert that any of the statements actually made in the 2002 article is false. The article notes, as example, that Apex tested its hips for torsional strength by ISO standards (Ex. 1 at 5). Plaintiffs do not allege that the tests were not performed as related.

Plaintiffs also cite, at Complaint ¶ 31, a 2003 Apex brochure as an example of alleged promotion. That 2003 brochure is attached as Exhibit A. Exhibit A contains statements to surgeons based on non-controversial geometry. The whole idea of a multi-piece artificial hip is to allow the surgeon to replicate the patient’s original hip structure by providing choices as to length of stem and angle (lateral offset) of the head. Single-

piece artificial hips do not allow for this fine tuning. Varied lateral offsets decrease the chance of dislocation of the head from the socket, giving the surgeon the chance to “optimize stability.” See Ex. A. Choices on stem length allow the surgeon to replicate the patient’s leg length giving “accurate leg length.” See id. The Apex Modular Stem feature of flutes that are embedded in the femur allow for flexible alignment of the hip and provide torsional stability of the stem on the bone.

Nothing in this brochure is a representation or warranty to any consumer. Further, as a matter of geometry and sense, the claims actually made are accurate. Moreover, the statements in Exhibit A are never attacked in the Complaint. While ¶ 31 of the Complaint references this brochure, the actual statements made in the brochure, to surgeons, are not alleged to be false. No claim of defect suggests that Apex hips led to dislocations as opposed to stability in the hip socket. Nothing in the Complaint asserts that leg lengths were not accurate or that the Apex hips failed due to alignment of the proximal stem or due to the flutes mentioned in the 2003 brochure. Since those are the statements made in the 2003 brochure, references to that brochure in the Complaint do not support any claim of misrepresentation, defect or injury.

Exhibit 1 to the Opposition also makes plain that there were standards met by and tests conducted on the Apex hip to achieve FDA approval. See Ex. 1 to Opposition at 2 (510K Summary). Plaintiffs do not and cannot allege that these tests were not passed or that the tests and standards set by the FDA were inadequate. There can be no compensable loss based on any failure to meet the criteria, set by the FDA, that made the Apex hip substantially equivalent to other devices marketed in interstate commerce. See Ex. 1 to Opposition at 3-4 (Department of Health & Human Services letter, August 4,

2000). The claim of injury in not receiving the benefit of a bargain is therefore illusory as the Apex hip did meet the standards, set and enforced by the government, applicable to Apex and to competing FDA approved hip devices that the surgeons for Plaintiffs might have chosen.<sup>1</sup>

#### IV. PLAINTIFFS FAIL TO ALLEGE AN INJURY TO SUPPORT ANY CLAIM

No matter what state laws apply, the injury alleged by Plaintiffs is elusive. While Plaintiffs note the discomfort associated with implanting hips in the first instance, Opposition at 2-3, that physical intrusion is not the result of any “defect” in the Apex hip; the surgery was necessary to address the Plaintiffs’ presenting condition regardless of the device implanted. It is a fair presumption that Plaintiffs do not now want a replacement hip for the Apex, entailing a second round of surgery not medically necessary for their functioning replacement.

It appears that Plaintiffs model their injury on a loss of the benefit of the bargain theory, but the nature of that loss for a functioning device is difficult to grasp. The chance of future injury is not usually recoverable, in Massachusetts or anywhere else.

See, e.g., Anderson v. W.R. Grace & Co., 628 F. Supp. 1219, 1231 n.6 (D. Mass. 1986).

Plaintiffs have now placed before the Court an FDA record noting that relevant tests on the Apex device were completed to the FDA’s satisfaction. See Ex. 1 to Opposition at 3-

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<sup>1</sup> In their Opposition, Plaintiffs make reference to one article on hip implant failure. Opposition at 16. Reference to one article in the Opposition does not supply the pleading requirement of alleging Apex failures outside the industry norm. While a dispute about the facts of failure rates may be a subject for discovery, the article cited by Plaintiffs is a survey that they selectively and inaccurately cite. Plaintiffs cite the rate for fracture of the metallic femoral stem at .27%, but femoral stem fracture is not the alleged failure mechanism of the Apex hip. Further, the total failure rate reported in this survey is 3.38%. More comprehensive failure rates from the Swedish Hip Arthroplasty Registry show a ten year survival rate of hip implants to the end of 2007 at 93.6%, meaning the ten year failure rate as of 2007 was 6.4%. See SAHLGRENSKA UNIVERSITY HOSPITAL DEPARTMENT OF ORTOPAEDICS, SWEDISH HIP ARTHROPLASTY REGISTRY ANNUAL REPORT 2007 42-43 (2007), <http://www.jru.orthop.gu.se>. Data from a Registry is inherently more reliable than a survey. The Apex hip has a higher survival rate than reported in this industry standard reference and is well within the range of failures reported in these two articles.

4. There were federal standards to be met before the FDA approved the Apex hip as substantially equivalent to other artificial hips. Plaintiffs make no claim that those standards and tests were not met. Plaintiffs do not and cannot allege that the FDA was mistaken in its conclusion that those tests established the Apex hip as the equivalent of other hips approved by the FDA. Should Massachusetts law apply, the Iannacchino reasoning on benefit of the bargain applies neatly to this case. If the claim of injury is intended to be based on alleged failure to meet a government standard, Plaintiffs do not allege any such failure or identify any applicable government standard. If the injury is based on an allegation of defect not based on some objective standard “legally required by and enforced by the government, a claim of economic injury based on overpayment *lacks the premise that the purchase price entitled the plaintiffs to a product that met that standard.*” Iannacchino, 451 Mass. at 633 (emphasis supplied). Plaintiffs simply have not alleged that the Apex hip was defective as against any definable standard or that the device was not equivalent to comparable devices.

Plaintiffs make much of a redesign of the Apex hip after they received their implant, but post-event investigation or re-designs are not admissible to prove liability in a case like this where no personal injury or injury to property is alleged. Id. at 634.

If Oklahoma law were to apply, Plaintiffs claims fail as they affirmatively allege that they have no actual physical injury or property damage. Such actual injury is required to plead a claim under Oklahoma law. See Walls v. American Tobacco Co., 11 P.3d at 630.

V. BREACH OF CONTRACT AND UNJUST ENRICHMENT COUNTS SHOULD BE DISMISSED

Plaintiffs assert that “there can be little dispute that [they] were the intended third party beneficiaries” of contracts between Apex and the hospitals, surgical centers and/or health insurance companies that purchased Apex hips. Opposition at 20. To the contrary, Plaintiffs assert without basis in alleged fact or logic that they were intended beneficiaries rather than mere incidental beneficiaries of commercial transactions to which they were strangers. Incidental beneficiaries of contracts do not have any rights to enforce the contract obligations. Miller v. Mooney, 431 Mass. 57, 62 (2000) (holding that parties must “clearly and definitely” intend the beneficiaries to benefit from the contract). While Plaintiffs allege that there “must” be contracts between Apex and the actual purchasers, they neither allege the explicit intent of the contracting parties to benefit Plaintiffs and give them the right to enforce the contract nor do they even identify the parties. That intent by identified parties is the essential element of a third party beneficiary claim. See Restatement (2d) of Contracts § 302.

The failure to allege any identifiable contract makes this case less a candidate for survival than the contract referenced in Brown v. Quest Diagnostics, LLC, No. 08-11517-RGS, 2008 WL 5236033, at \*9, \*10 (D. Mass. Dec. 16, 2008), where the claimant at least alleged the identity of the parties to the alleged contract. Here, Plaintiffs give no fair notice of the claim they intend to pursue.

The claim for unjust enrichment is pled generically and must be dismissed for several reasons. First, this equitable remedy is derivative of the other misrepresentation and fraud claims made by Plaintiffs. There is no unjust enrichment claim where adequate remedies at law exist. E.g., In re: Lupron Marketing and Sales Practice Litigation, 295 F.

Supp. 2d 148, 182 (D. Mass. 2003). If Plaintiffs' claims have merit, they have a remedy at law; if their allegations fail, then the derivative unjust enrichment claim fails, too.

Further, Plaintiffs now acknowledge that Plaintiffs and the class were not purchasers of the Apex hip, that purchase being made by others. See Opposition at 22, n. 10. There is no unjust detriment to Plaintiffs that needs a remedy.

VI. CONCLUSION

The Complaint should be dismissed in its entirety for the reasons set out in the Memorandum and in this Reply.

REQUEST FOR ORAL ARGUMENT

Defendant requests oral argument on its Motion to Dismiss.

Respectfully submitted

OMNI LIFE SCIENCE, INC.

By its attorneys

/s/ James J. Dillon

James J. Dillon (BBO #124660)

Brian C. Carroll (BBO #658940)

Diana Jong (BBO #669805)

FOLEY HOAG LLP

155 Seaport Boulevard

Boston, MA 02210-2600

Telephone: (617) 832-1000

Fax: (617) 832-7000

jdillon@foleyhoag.com

bcarroll@foleyhoag.com

djong@foleyhoag.com

Dated: September 23, 2009

**CERTIFICATE OF SERVICE**

I, James J. Dillon, hereby certify that the above document filed through the ECF system will be served electronically to the registered participants as identified on the notices of electronic filing and will be served by U.S. mail, postage prepaid, to those indicated as non-registered participants on September 23, 2009.

/s/ James J. Dillon  
James J. Dillon